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09/518,642	03/03/2000	Grady Lynn Holt	A7534	5821

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EXAMINER	
LEUNG, JENNIFER A	
ART UNIT	PAPER NUMBER
1764	

DATE MAILED: 01/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/518,642	HOLT, GRADY LYNN	
	Examiner	Art Unit	
	Jennifer A. Leung	1764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *8-10,13,14 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,11,12,15,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

1. Applicant's amendment submitted on September 22, 2003 has been received and carefully considered. Claims 1-18 remain active. Claims 8-10, 13, 14 and 16 are withdrawn from consideration. Claims 1-7, 11, 12, 15, 17 and 18 stand rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1, 3, 4, 7 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (U.S. 3,603,484) in view of Chaignay (FR 2 590 519) and J. De Santa et al. (US 3,221,917).

Regarding claims 1 and 17, Ogle (FIG. 1-9; column 3, lines 1-65) discloses a compressible reactor/system comprising:

- a single-use vessel (i.e. outer container **10**) holding a volume of treatment chemical and a frangible container (i.e. inner container **48** having a pierceable cap **52**, hence "frangible") which may contain a toxic chemical, depending on the intended use (column 1, lines 9-12; column 2, lines 14-16); said single-use vessel **10** having a compressible section (i.e. accordianlike undulations **32**) and a lower treatment portion (i.e. the chamber, as defined by the walls of outer container **10**) having a means for fixing the frangible container **48** to the lower treatment portion (i.e., bottom most undulation **32** snap fitted to indentations **50**; column 3, lines 27-31; see also FIG. 15 and 16 for another configuration);
- a cover (i.e. end closure **14**) fastened to said single use vessel **10**; and

- an impact member (i.e. projection **34**) fixed to said cover **14**, wherein upon compression of said compressible section **32**, said impact member **34** approaches and breaks said frangible container **48**, **52** (FIG. 3).

Ogle discloses that for the means for compressing the compressible section, "the user simply compresses the package in an accordianlike fashion as shown in FIG. 3 to cause the projection **34**... to pierce the cap **52** on the inner container **48**," (column 3, lines 37-41). However, Ogle is silent as to whether the user's means for compressing may comprise a jack and compression support frame, such that the jack is operative to extend between the cover and compression support frame to compress the compressible section. In any event, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to substitute a jack and compression support frame for the means for compressing in the apparatus of Ogle, on the basis of suitability for the intended use and absent showing any unexpected results thereof, since the provision of mechanical or automated means to replace manual activity was held to have been obvious, *In re Venner* 120 USPQ 192 (CCPA 1958); *In re Rundell* 9 USPQ 220 (CCPA 1931), and the substitution of one known equivalent technique for another may be obvious even if the prior art does not expressly suggest the substitution, *Ex parte Novak* 16 USPQ 2d 2041 (BPAI 1989); *In re Mostovych* 144 USPQ 38 (CCPA 1964); *In re Leshin* 125 USPQ 416 (CCPA 1960); *Graver Tank and Manufacturing Co. v. Linde Air Products Co.* 85 USPQ 328 (USSC 1950). Furthermore, the use of jacks, coupled with a support frame, as a means for compressing is conventionally known in the art, as evidenced by Chaignay. In particular, Chaignay (Abstract, Figures) teaches a small hydraulic press comprising a jack (FIG. 2) attached to the upper surface **5** of a surrounding frame (comprising components **1**, **2**, **5**),

wherein in operation, an object (i.e. the compressible reactor of Ogle) which is placed upon the base of the frame is compressed by the jack via extension of the extendable shaft **20** (FIG. 1).

In view of the newly added limitations, the collective teachings of Ogle and Chaignay are silent as to compressible section **32** being located in the upper portion of the apparatus. In any event, it would have been an obvious design choice for one of ordinary skill in the art at the time the invention was made to select such a location for the compressible section **32** in the modified reactor/system of Ogle, because whether the compressible section is located in the upper portion of the container or the lower portion of the container serves the substantially identical function of providing a means for actuating the impact member **34** so as to approach and pierce frangible container **48**. Such concept is evidenced by J. De Santo et al., who teach an apparatus adapted to contain two different types of fluid in separate compartments, whereby the fluids can be mixed together when desired for use. In particular, the apparatus comprises a single use vessel **10** having pleats **14** located in an upper portion of the vessel (see FIG. 2). Upon expansion of pleats **14** (see FIG. 5) a central valve stem **38** is actuated upwards. Upon compression of pleats **14**, the central valve stem **38** would, inherently, be actuated downwards. Thus, lower compressible section **32** of Ogle and upper pleats **14** of J. De Santo comprise substantial equivalents structurally and functionally, and it has been held that the substitution of known equivalent structures involves only ordinary skill in the art. *In re Fout* 213 USPQ 532 (CCPA 1982); *In re Susi* 169 USPQ 423 (CCPA 1971); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *In re Ruff* 118 USPQ 343 (CCPA 1958).

Regarding claim 3, Ogle discloses frangible container **48**, **52** may be made of glass (column 3, lines 21-22), hence comprising a "glass ampoule".

Regarding claim 4, although Ogle is silent as to whether frangible container **48**, **52** may contain a chemical weapon material, Ogle further discloses container **48**, **52** and vessel **10** are "generally applicable to the storage and mixing... of *any* two reactive or nonreactive liquids or to the mixing of any liquid and solid," (column 1, lines 9-12), and the device is, "particularly adapted for the handling of reactive, *toxic* and/or noxious chemicals," (column 2, lines 14-16). Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to select an appropriate chemical, such as a chemical weapon material, for the chemical in the modified apparatus of Ogle, on the basis of suitability for the intended use and absent showing any unexpected results thereof.

Regarding claim 7, Ogle discloses, "closure **14**... has a lip **24** which engages and forms a *seal* on the upper end **26** of container **10**," (column 3, lines 5-7). A gasket may be defined as, "any of a wide variety of seals or packings used between matched machine parts or around pipe joints to prevent the escape of a gas or fluid," (The American Heritage® Dictionary of the English Language, Fourth Edition. Copyright © 2000 by Houghton Mifflin Company). Therefore, lip **24** of Ogle meets the claim of a "cover gasket".

3. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (US 3,603,484) in view of Chaignay (FR 2 590 519) and J. De Santa et al. (US 3,221,917), as applied to claim 1 above, and further in view of Loper (U.S. 3,087,638).

Ogle (FIG. 1-8; column 3, lines 2-4) discloses cover **14** may comprise a means for sampling the mixed chemicals, wherein the means comprises a dispensing spout **16** having a fluid passage **18**. However, Ogle is silent as to whether the means may comprise a septum formed within said cover. In any event, it would have been an obvious design choice for one of

ordinary skill in the art at the time the invention was made to select a septum for the means for sampling in the modified apparatus of Ogle, on the basis of suitability for the intended use and absent showing any unexpected results thereof, since the use of a septum as a means for sampling is conventionally known in the art, as evidenced by Loper. In particular, Loper teaches a septum (piston plug **30**) for allowing a user to sample the contents of a container **15** using a piercing needle, wherein the needle is inserted through the penetrable material on the topside **29**, **29a**, **29b** of the piston plug (Figures; column 1, lines 9-28; column 2, lines 70-73; column 3, lines 43-51). Furthermore, substitution of known equivalent structures involves only ordinary skill in the art. *In re Fout* 213 USPQ 532 (CCPA 1982); *In re Susi* 169 USPQ 423 (CCPA 1971); *In re Siebentritt* 152 USPQ 618 (CCPA 1967); *In re Ruff* 118 USPQ 343 (CCPA 1958).

4. Claims 5, 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (US 3,603,484) in view of Chaignay (FR 2 590 519) and J. De Santa et al. (US 3,221,917), as applied to claim 1 above, and further in view of Bolduc (U.S. 5,064,121).

Regarding claims 5 and 6, Ogle discloses the frangible container may comprise indentations **50**, "adapted to receive the inner edge of the bottom most of the accordionlike undulations **32** with a snap fit," such that, "the container **48** is restrained from longitudinal movement with respect to the outside container **10**," (column 3, lines 25-31), essentially functioning as a holding means for container. However, Ogle is silent as to whether the holding means may comprise a cradle for holding the container, wherein the cradle comprises penetrations. Bolduc (FIG. 1, 3, 6) teaches an apparatus for separately storing, mixing and dispensing two chemicals, similar to the apparatus of Ogle, wherein the apparatus comprises a single-use vessel (external bottle or container **11**) holding a frangible container (ampule or vial

49), wherein the mixing of the chemicals is initiated by the breaking container **49** with an impact member (push rod **42**). In particular, container **49** is held in place by a cradle (holder **53**), which comprises a plurality of penetrations (vent holes **55**). It would have been obvious for one of ordinary skill in the art at the time the invention was made to provide a cradle comprising penetrations for the holding means in the modified apparatus of Ogle, because holder **53** provides a rigid support for frangible container **49** while facilitating mixing of materials via penetrations **55**, as taught by Bolduc (column 3, lines 9-12, 48-50; column 7, lines 2-5, 58-61). Furthermore, substitution of known equivalent structures involves only ordinary skill in the art.

Regarding claim 18, Ogle (FIG. 1-8; column 3, lines 1-50) discloses a method of treating a toxic chemical (column 2, lines 14-17) using the apparatus as disclosed in claim 1 above, comprising the steps of:

- placing the frangible container (comprising inner container **48**, cap **52**) in said single-use vessel **10** so that said frangible container **48**, **52** is internally aligned with an impact member (projection **34**);
- inserting the treatment chemical (column 1, lines 9-12; column 4, lines 28-37) into said single use vessel **10**; and
- sealing said single-use treatment vessel **10** by providing an end closure **14** having a lip **24** that engages and forms a seal on the upper end **26** of container **10**;

wherein the elements are, "assembled in the fashion as shown in FIG. 1." (column 3, lines 34-37). However, Ogle is silent as to the particular order for conducting the steps above for obtaining the structure shown in FIG. 1.

Bolduc (FIG. 1, 3, 6; column 8, lines 23-34) teaches an apparatus for mixing and

dispensing two chemicals that are separately stored, similar to the apparatus of Ogle, wherein the method for using the apparatus comprises the steps of:

- first, placing a frangible container (sealed ampule **49**) into a single-use vessel **11** so that said frangible container **49** is internally aligned with an impact member (push rod **42**);
- second, inserting a treatment chemical (i.e. material **17**) into said single use vessel; and
- third, sealing said single-use treatment vessel **11** with cap **18**.

It would have been obvious for one of ordinary skill in the art at the time the invention was made to conduct the steps according to the order of Bolduc in the method of Ogle, since both processes are substantially identical or equivalent in terms of function, manner and result, and it has been held that the where the processes are substantially identical or equivalent in terms of function, manner and result, transposition of process steps or the splitting of one step into two does not patentably distinguish the processes. *Ex part Rubin* 128 USPQ 159 (PO Bd PatApp 1959).

Ogle further discloses that following assembly, "when it is desired to admix the two ingredients, the user simply compresses the package in an accordionlike fashion as shown in FIG. 3 to cause the projection **34** with its sharp cutting edges **38** to pierce the cap **52** on the inner container **48**," (column 3, lines 37-41), which *in the modified apparatus*, would comprise the step of operating the jack so that a force is exerted on the compressible section (see comments made with respect to Chaignay in claim 1 above). However, Ogle is silent as to shaking the vessel to facilitate mixing between the treatment chemical and said toxic chemical. In any event, it would have been obvious for one of ordinary skill in the art at the time the invention to shake the contents of the vessel in the modified method of Ogle, since it is well known in the art that agitation by means of shaking facilitates mixing. Such is evidenced by Bolduc, who teaches that

"mixing of materials can be facilitated by shaking dispenser **10**." (column 7, lines 54-58).

5. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (US 3,603,484) in view of Chaignay (FR 2 590 519), J. De Santa et al. (US 3,221,917) and Bolduc (US 5,064,121). The same comments with respect to Ogle, Chaignay, J. De Santa and Bolduc apply (see claims 1 and 18 above).

6. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (US 3,603,484) in view of Chaignay (FR 2 590 519), J. De Santa et al. (US 3,221,917) and Bolduc (US 5,064,121), as applied to claim 11 above, and further in view of Loper (U.S. 3,087,638).

Ogle (FIG. 1-8; column 3, lines 2-4, 48-50) discloses the step of dispensing or "sampling" the mixed chemicals from the apparatus via a sampling means comprising a dispensing spout **16** and a fluid passage **18**, but is silent as to the sampling means comprising a septum. The same comments with respect to Loper apply (see claim 2 above).

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogle (US 3,603,484) in view of Chaignay (FR 2 590 519).

The same comments with respect to Ogle and Chaignay apply (see claim 1 above).

Response to Arguments

8. Applicant's arguments regarding the rejections of claims 1-7, 11, 12, 17 and 18 have been considered but are moot in view of the new grounds of rejection, as necessitated by the amendments to claims to recite "an upper compressible section" and "a lower treatment portion".

9. Applicant's arguments with respect to the rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Ogle (US 3,603,484) in view of Chaignay (FR 2 590 519) have been

fully considered but they are not persuasive, since it is noted that the claim still recites "a compressible section" and "a treatment portion", with no limitation of location to an upper or lower portion, respectively.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

* * *

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A. Leung whose telephone number is (571) 272-1449. The examiner can normally be reached on 8:30 am - 5:30 pm M-F, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Glenn A. Caldarola can be reached on (571) 272-1444. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

Jennifer A. Leung
December 17, 2003

Hien Tran

HIEN TRAN
PRIMARY EXAMINER